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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/825,965

04/15/2004

Kenneth T. Heruth

1023-361US01

8233

28863

7590

10/02/2006

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EXAMINER

GEDEON, BRIAN T

ART UNIT

PAPER NUMBER

3766

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/825,965	HERUTH ET AL.	
	Examiner	Art Unit	
	Brian T. Gedeon	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29,31-49 and 69-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29,31-49 and 69-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/15/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/1/06, 6/16/06, 3/21/06, 1/29/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1, 2, 6, 8-19, 22-25, 29, 31-36, 38-44, 47-49, 69, 72-76, and 79-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon et al. (US Patent no. 6,449,508) in view of Stone et al. (US Patent no. 6,102,874).

In regard to claims 1, 6, 8-10, 13-16, 19, 22-24, 29, 31-33, 36, 38, 39, 41, 44, 48, 49, 72-76, 80 and 81, Sheldon et al. describe an implantable medical device 10, in the form of a pacemaker. Inherently a pacemaker outputs a therapy to a patient. The scope of Sheldon et al. should not be limited to pacemakers alone, but to implantable medical devices in general, col 3 lines 4-9. Processor 122 is the central processing unit and may be an off-the-shelf microprocessor, col 4 lines 39-41. The implanted device is fitted with an activity sensor circuit 21, which will produce an activity signal, col 3 lines 51-53. The activity sensor 21 can be used in conjunction with a cardiac demand parameter-measuring sensor in order to help measure and identify a level of cardiac demand, col 3 lines 40-50. The Examiner interprets this as essentially as providing the capability of associating determined activity levels with parameters for therapy associated with cardiac demand. The activity sensor 21 produces activity counts 42, and ranks them according to a threshold comparison, col 6 lines 11-21 and col 8 lines

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41-44. The activity counts are ranked low, medium, or high, which the Examiner interprets as being an "activity metric value", and considers that the act of ranking the activity counts could be implemented on a list. As shown in figure 2, or embodied with a cardiac demand parameter sensor, col 3 lines 40-50, the device of Sheldon et al. substantially shows the structure, whose features are capable of performing the method of associating activity data with therapy parameters. However, Sheldon et al. do not teach the step for determining the average amount of time an activity level remains above a threshold. Stone et al. describe an implantable medical device for tracking patient functional status, in which the sum of activity counts in a given time period are divided by the number of periods, in order to determine the amount of counts above a threshold level, col 14 lines 34-48. These counts are referred to as "active" counts. Because the device of Stone et al. keeps track of how many activity counts are above a threshold, or that are in an "active" state, in a given period, the device indirectly determined the amount of time that an activity count is "active", and it would not be beyond one of ordinary skill in the art to be able to average these time periods together. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above references to measure activity levels and determine appropriate therapy values, since Sheldon et al. teach that activity levels are useful for diagnosis of certain disorders, and that knowledge of patient activity data can provide a window into the health of a patient.

In regard to claims 2 and 25, Sheldon et al. disclose that a band pass filter is used to filter the acquired signals and isolate the appropriate frequencies typically within the

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range of 1-10 Hz. This is within the range claimed by Applicant, and one of ordinary skill in the art would be able to extend that range to 0.1 Hz.

In regard to claims 17, 18, 40, 42, and 43, Sheldon et al. don't explicitly describe a display device, but do imply that their device may be embodied with a display since they teach that the acquired data can be stored in a histogram and be made available to display, col 10 lines 30-48 for diagnostic, therapeutic, or research purposes.

In regard to claims 11, 12, 34, and 45, Sheldon et al. state that the activity sensor 21 is used in conjunction with a minute ventilation sensor 22 to produce a signal indicative of cardiac demand, col 3 lines 51-55. This sensor senses a physiological values, in particular relating to respiration rates and volumes.

2. Claims 3, 26, and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon et al. (US Patent no. 6,449,508) in view of Stone et al. (US Patent no. 6,102,874) further in view of Thompson (US Patent no. 5,233,984).

Sheldon et al. in view of Stone et al. substantially describe the invention as claimed, except for determining if the patient is awake from the activity sensor.

Thompson discloses an implantable multi-axis activity sensor, and teaches that activity sensors give indication of a patient's state of rest or activity, col 2 lines 10-17, which the Examiner interprets as meaning that an activity sensor can determine if a patient is awake. Therefore it would be obvious to one of ordinary skill in the art at the time the invention was made to determine the rest state of a patient since Thompson teaches it.

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3. Claims 4, 5, 27, 28, 70, 71, 77, and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon et al. (US Patent no. 6,449,508) in view of Stone et al. (US Patent no. 6,102,874) further in view of Bornzin et al. (US Patent no. 5,514,162).

Sheldon et al. in view of Stone et al. substantially describe the invention as claimed except do not teach the act of calculating a mean or median of activity data. Bornzin et al. teach using an activity deviation histogram, in which the median activity measurement is compared to a set of normal activity deviation values, interpreted to be threshold values, in order to determine the activity level of a patient, col 6 lines 34-48. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to compare median values of two sets of data since the median is a well-known parameter in descriptive statistics.

4. Claims 20, 21, 45, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon et al. (US Patent no. 6,449,508) in view of Stone et al. (US Patent no. 6,102,874) further in view of McClure (US Patent no. 6,659,968).

Sheldon et al. in view of Stone et al. substantially describe the invention as claimed except do not teach that the implantable device can be a neurostimulator. Sheldon et al. state that their device should not be limited to pacemakers alone, but to implantable medical devices in general, col 3 lines 4-9. Stone et al. states that their device could be embodied as an implantable drug pump or any device with similar circuitry to an implantable stimulator, col 7 lines 62-65. McClure discloses an activity monitoring device which includes an activity sensor and is embodied as a spinal cord stimulator, as well as in a temporary system for trial purposes, col 2 lines 34-46 and col

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3 lines 4-10. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to embody the structure and perform the method as claimed in any kind of implantable medical pulse generating device.

Double Patenting

5. Claim 1-6, 8-29, 31-49 and 69-82 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of copending Application No. 11/106,051; and claims 1, 2, 4-6, 9-13, 16-18, 20-22, 25-28, 30-32, and 35-37 of copending Application No. 11/081,873. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims of co-pending application recite methods and structure regarding collecting patient activity data and correlating said data to therapy values.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272 3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272 6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian T. Gedeon
Patent Examiner
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BTG